

RESPONSE TO OFFICE ACTION:

Objections to Claims 11 and 13: Claim 11 has been amended as suggested to replace "or" with "and". Claim 13 has been amended as suggested, to read "at least one absorbent pad" at each occurrence.

Claim rejections: Claims 13 and 17 have been allowed over the prior art. Aside from the correction to claim 13, no changes have been made to these claims. Claim 12 now depends from claim 17, as do new claims 36 and 37.

Claim 1 is cancelled, and its dependent claims amended so that they depend on claim 11 or on claim 17.

Claim 11, an independent claim, was in a previous office action deemed to be allowable if in independent form. However, it now stands rejected under 103(a) over Polson, and further in view of Zhu. To simplify the consideration of claim 11, Applicant has amended it so that claim 11 further contains the limitation of former claim 2, which is cancelled, and the additional limitation that the protecting material be water soluble. The amendment is supported by at least paragraphs 0035 - 0039 (p. 12 - 15). It is believed that claim 11 as amended is distinctive over the prior art cited by examiner, or as cited in the attached IDS.

Claim 2 was rejected under 102 over Kreamer (US 4,577,631). Kreamer applies a coating of cyanoacrylate to a Dacron graft, and then puts a temporary sleeve of Dacron over the cyanoacrylate coating to protect it while the graft is being passed through the aorta and other arteries. It is not clear to applicants why the cyanoacrylate will not cure and lock the two Dacron layers together; the method is dangerous and perhaps unworkable. However, to distinguish applicant's coating from Kreamer's sleeve, the coating herein is characterized as water-soluble. It is believed that the rejection over Kreamer is not applicable to the claim as amended.

Claim 11 was rejected over Poulson et al US 5,487,897 as cited against claim 1, and further in view of Zhu et al US 6,589,269. Polson teaches the formation in-situ of a fibrous, porous material, which is created by the coagulation of a polymer when its organic solvent diffuses away and it is contacted by water. (Abstract; col 1 line 60 through col 2 line 59.) The material is biodegradable (col 1 line 50). This degradability is a critical feature of the Polson et al invention, and is cited as an affirmative benefit compared to Gore-Tex (porous PTFE) and porous cellulose acetate (Millipore), see col. 1 lines 24 - 39, where such materials are actively disparaged. An example (col 20 line 36 ff - Example 1) of the Poulson material is 37% D,L-polylactide (biodegradable polymer) in N-methyl 2-pyrrolidone solvent.

The Poulson material is capable of being an adhesive (col 19 lines 24-56.) It can be formed into a film and put in a peridontal pocket (Ex 4-6, col 21-22). But there is no showing that the precipitated polylactide sponge would have any significant tensile strength, and numerous showings that it has little strength (e.g. col 20 line 65 - col 21 line 5.)

In contrast, applicant is using preformed materials, particularly PTFE and fibrotic polypropylene stimulator materials, as reinforcing materials for tissue, gluing them in place. Moreover, in the amended claim 11, the glues are pre-coated with a water-soluble coating to prevent premature attachment of the graft to itself, for example, during implantation, or to tissue other than the site of the repair. Poulson alone does not make it obvious to do this. In the rejection, it is stated that applicants have not disclosed that applying adhesive to the prosthetic provides an advantage or solves a problem. However, applicant's paragraphs 0035 - 0039 provide such disclosure, as do paragraphs 0046-0047 and 0060 - 0064 (p. 12 - 18).

Zhu et al applies patches to tissue for reinforcement. Using an applicator, a patch (not having an adhesive) is placed over a defect internally to a patient, and then glue is dispensed through a lumen of the device to adhere the patch to tissue, particularly to seal a blood vessel after using it for access to the heart, etc. (col 4 lines 5 - 11.)

In contrast, applicants apply glue to one side of the patch before application (e.g., applicant's claim 11; specification, para. 0035 - 0039), preferably at the time of

manufacture, and also apply a coating to prevent the mesh and adhesive from sticking to itself until after implantation. This is a different procedure from that of Zhu - applicant coats the repair patch with adhesive before implantation, and overcoats the adhesive with a protective coating, while Zhu's device coats an implant after implantation. Different patch application devices are needed. Although one patch material is named in common (PTFE), it is difficult to see how Zhu alone would make applicant's invention obvious, nor how Poulson would in any way assist Zhu in making applicant's invention obvious, and particularly with the limitation of overcoating the adhesive.

It is believed that the analysis presented above shows that claim 11, as amended, is not reasonably made obvious by the cited references alone or in combination, and that claim 11 is patentable along with allowed claims 13 and 17. The other claims, being dependent on an allowable base claim, would likewise be allowable. Passage of the claims to issue is respectfully requested.

Sincerely,



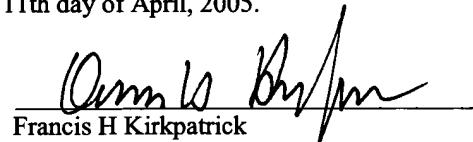
Francis H Kirkpatrick

Reg. # 35,219

978-790-7186; fax 978-256-3679

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with sufficient first-class postage attached, addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 11th day of April, 2005.


Francis H Kirkpatrick